IN THE U.S. PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant: Eric Begleiter

Confirmation No. 8373

Serial No.: 10/031,765

Art Unit: 1615

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Examiner: Susan T. Tran

For: Edible Holographic Products, Particularly Pharmaceuticals (as amended)

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV892895888US, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: October 19, 2006 Signature: Laurie Brown (Laurie Brown)

Declaration Under Rule 132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Eric Begleiter, hereby declare that:

1. I am the applicant in the above-identified application.

2. I received a Master of Science in Visual Studies in 1984 from the Massachusetts Institute of Technology majoring in advanced techniques of optical holographic display

technology. I received a fellowship at MIT's Center for Advanced Visual Studies between 1984 and 1991 where I continued to do research and lecture on holography and 3D spatial imaging techniques.

3. I have been working in applications of holography to edible materials for over twenty years. My work in the 1980's on holographic effects and images on candy and confections is in part described in U.S. Patent No. 4,668,523, my first patent in the field of edible holography.

4. In about 1986 I founded, and became President of, Edible Holographic Industries, which later became Dimensional Foods Corporation (collectively, "DFC"). A major commercial goal of DFC was to find cost-effective uses for edible forms of holography. As President of DFC, I have worked with various large food-manufacturing companies on overcoming numerous problems in the commercialization of edible holography on edible products. This work included extensive research in applying holograms to such products as chocolate and hard candy. I also began to consider whether edible holography could be applied to pharmaceuticals. Much of this work has focused on extending the life of edible holograms and developing new products.

5. In about 1996 I formed and became president of LightVision Confections LLC. a subsidiary of DFC, ("LightVision"). Since 1996 LightVision has been almost exclusively involved in the development and manufacture for sale of edible forms of holographic candy, particularly hard candy, in a LightVision factory in Ohio.

6. From 1997 to 2006 I have been a project leader for a major pharmaceutical corporation with the objective of developing new holographic pharmaceutical products (edible dosage forms), manufacturing processes, and equipment for the manufacture of these products.

7. I have read the file history of the above-identified application, including the references of record and the non-final Office Action mailed April 19, 2006, now pending. In particular, I am the patentee of European Patent No. 0 217 821 ("the EP '821 patent"), the principal reference now applied against the pending claims, and the corresponding U.S. Patent No. 4,168,523 ("the U.S. '523 patent"), which was cited against the above-identified application in the first Office Action on the merits, and overcome. I am also the author of the secondary reference also now applied against the pending claims, the 1991 article "Edible Holography: The Application of Holographic Techniques to Food Processing," pp. 102-109 of The Proceedings of SPIE - The International Society for Optical Engineering (the "SPIE Article").

8. A major technical consideration in all of my work has been that the microscopic patterns of ridges and grooves that produce a holographic display are not only extremely small -- a typical groove depth being ½ to 1 micron (1/1,000,000 meter) -- but also the edible material flows, expands, and otherwise changes its shape and dimensions in response to changes in temperature, humidity, and applied stresses. These stresses can arise when a dehydrated film (also termed herein as "cast" or "deposited") containing a

holographic pattern is demolded, or through later handling and use of the demolded product. The stability of the holographic pattern also depends on the product itself. For example, sugar products such as lollipops are strongly hydroscopic. A holographic element on a lollipop interacts with the moisture that the lollipop attracts and holds to degrade the holographic display. In general, the holographic layers or elements I have made and used in edible holography are more akin to a layer of living tissue than to a rigid, inanimate structure. Also, the lollipops and like confections made and sold by LightVision place the holographic relief on a large (2-inch or more diameter), flat face of the food product.

9. In creating a successful holographic display for a pharmaceutical dosage form, it was necessary to overcome many problems with the technology described the EP '821/U.S. '523 patents and SPIE Article. These problems include those on pages 2 to 4 of my present application. Until 1997, the only holographic pharmaceutical product that I and/or my companies DFC and LightVision created, and the only ones then known to me, were the experimental, cold-compressed, powder tablets described in the 1991 SPIE article. However, a major problem with these tablets is that the diffraction effects (holographic displays) were not bright or stable; they lasted only a few weeks. In large part this tablet was not successful because the diffraction structure of such a tablet is extremely delicate, having only a micron-scale depth. In addition, the punch used became easily clogged by the types of powders used, and wore out within a few cycles because of the high compression pressures. Cold compression was used in part because

heat was known to degrade the efficacy of the active ingredients of pharmaceuticals, and was therefore contra-indicated.

10. The casting/dehydration process used before the present invention to create the edible holograms described in the '821 EP patent, the '523 U.S. patent, the SPIE Article, as well as the candies manufactured by LightVision, had numerous problems that directed me against using that process, or the cast product, for a pharmaceutical product. For example, most pharmaceuticals are tablets. But tablets are not thin films; they cannot be effectively dehydrated in the same way that a thin liquid layer poured into a mold can dry to form a thin solid film. Dehydrated edible holographic films that are cut, or otherwise formed, into dosage form-sized elements, could not, prior to the present invention, be applied effectively by me to existing tablet products without pealing off, being misaligned, "bubbling," or without the glues and other bonding materials becoming visible and marring the surface of the tablet or interfering with the delicate structure of the hologram. Other problems unique to pharmaceuticals are detailed in the above-identified application, hereinbelow, and in the Remarks of the Amendment filed herein on August 10, 2004, pages 14-23.

11. I conducted experiments with heat stamping and ablation on surfaces of hard candy mixed with fats and starches as described in my 1991 SPIE Article. Because of the extreme difficulty in obtaining any holographic image on such materials, my comments in the SPIE Article reflect not that the resulting product was a commercially viable candy, and certainly not that it was a successful pharmaceutical dosage form, but rather

that it was, as I termed it in 1991, "encouraging," to see any transfer of a holographic pattern at all. Specifically, experimental holographic patterns that were produced in these hard candy materials using non-deposit techniques such as heat stamping were very unstable; the images lasted only a few weeks, even under perfect conditions. With such an extremely fine structure of the hologram on these materials, the holographic image or effect would disappear if exposed to any humidity, such as merely breathing on the product. These experimental non-deposit holographic candies were not stable, whether taking the definition of "stable" as defined for pharmaceutical dosage forms in the above-identified application, or even for candies or other food products obtained with dehydration techniques.

My SPIE Article, at page 105, states that the products described there had a product life of "9 months or less." This is in fact the product life that I observed for holographic food products, whether experimental or the commercially produced LightVision holographic candies. (While the EP '821 patent mentions the use of a humidity barrier in the food product, these barriers did not work well enough in food products to increase stability meaningfully.) While this 9 month or less life is acceptable for certain food products, this is not it within the definition of "stable," as presently claimed for pharmaceuticals. Other sugar and chocolate materials mentioned in the SPIE Article were deposited hot and cooled, but did not have the rapid setting characteristics of a thermoformable material, or anything like the stability needed to produce a viable pharmaceutical product. (A thermoformable material is thermally reversible -- it rapidly transitions from a solid to a liquid or vapor when heated, and then very rapidly transitions back to a solid when the heat is terminated and/or the material is cooled.)

12. When, in 1997, I focused my research on solutions to the problems of manufacturing a holographic pharmaceutical, it was unknown to me whether any materials, or any fabrication process, could produce a successful holographic pharmaceutical product. In particular, for the reasons detailed in Paragraphs 13 to 17 and 22-23 below, neither I, nor anyone else that I was aware of prior to the present invention, had the insight that edible, stable holograms for pharmaceutical dosage forms were even possible, let alone the possible use of a layer of an edible thermoformable material to receive and hold the holographic relief pattern.

13. HPMC and other materials had been used prior to the present invention to create cast/dehydrated holograms as a film, but these materials and films took an extended period of time to form by drying, and presented the other problems noted above and in the above-identified application; they were not considered by me to be a viable material for a holographic pharmaceutical dosage form. Experiments by me, or conducted under my direction, tried dehydrating pharmaceutical tablets coated with materials against a transfer grating. However, because of the lack of air circulation and effect of the liquid on the tablet, these experiments proved unsuccessful. Experiments were also tried in which dehydrated holographic films were applied to a tablet, but with the above-described problems, among others, of adhesion and marring of the surface.

14. The candy, confection and foodstuff products discussed in the EP '821 and SPIE Article are physically different from the thermoformed holograph pharmaceutical dosage

forms of the present invention, even though they both may use HPMC as one of their constituent materials. In part, this relates back to the differences, particularly in hydroscopic characteristics, of food products and pharmaceuticals. In part it also relates to the dehydration process of the prior art. It is slow, performed on a flat mold, and favors a type of film for both drying speed and the ability to remove the dried film from the mold without cracking the film, or otherwise destroying or degrading the film or the delicate, minute holographic pattern on the film. These cast films use plasticizers aimed, in type and proportion to other constituents, to promote the demolding process, especially by controlling cracking of the film as it is demolded and to control adhesion to the mold during drying and bonding to the candy after depositing. In contrast, thermoformable layers of the present invention can have thicknesses and constituent materials that are unworkable for cast films. The end food/candy product includes a holographic element on a sugar or chocolate-based product that is not a pharmaceutical dosage form. The holographic element and the food product interact with one another, and with the external stresses and the environment, in markedly different ways than a holographic pattern on a pharmaceutical dosage form. These prior art food and candy products have a shelf life of 9 months or less. They are not "stable" as defined and claimed in the above-identified application for pharmaceutical dosage forms. .

15. The fact that a material can be dehydrated does not mean that it is thermoformable or stable, that is, it can be heat-stamped, or made to flow rapidly, and then set rapidly and/or be stable for the expected product life of a pharmaceutical dosage form. And, my work has demonstrated that a material that can produce a holographic display on a food

product through dehydration does not mean that this same material can produce a holographic display on a pharmaceutical dosage form that is stable or thermoformed. For example, materials forming paper can be dehydrated, but they cannot be readily heat-stamped. I experimented with numerous materials in the 1990's to see if any could be cast and then heat-stamped. Many edible materials just burned, or needed a level of heat that would destroy the potential efficacy of the active ingredient(s) in the drugs. Some materials did receive a hologram, but were stable for only a few days or weeks, or had other visual defects, or partially stuck to a transfer plate that produced the holographic pattern, destroying both the hologram and the transfer plate. Other materials were not workable solutions for reasons of FDA approval requirements for pharmaceuticals. A materials that worked for holographic candies and foodstuffs made according to my '821 EP patent, my U.S. '523 patent, or my SPIE Article was not clearly workable in another product -- a stable pharmaceutical dosage form that produces a holographic display.

16. Despite my manufacture of holographic food products, and even after this experimentation, it was difficult for me to convince others that commercially viable pharmaceutical products could be manufactured. The large pharmaceutical company that I work with since 1997 threatened future funding for research on a holographic pharmaceutical dosage form. Additional research was funded and conducted into 1999 to solve the various problems encountered.

17. Through the research and development that began in 1997, it became clear that the requirements, in both materials and processes, for the production of a holographic

pharmaceutical product are very different than those for candies and like foodstuffs. Similarly, the requirements of a holographic pharmaceutical dosage form are very different from those of holograms used to decorate confections, candy or other foodstuffs. As one example, and as noted above in paragraph 9 with respect to the use of heat, the formation of the product cannot adversely effect the active compounds. As another example, the requirements of stability of the end holographic product are much more demanding. Another example is that a pharmaceutical dosage forms not use materials that require Governmental approvals around the world for use in pharmaceuticals. On information and belief, approval of a new ingredient, e.g. a new colorant, can cost millions of dollars worldwide. However, because of the industry perceived, but unmet, need for a non-chemical colorant, additional anti-counterfeiting measures, and a visual indication of a dosage forms storage, man-years of effort and significant expenditures continued to go into the project I led to produce a holographic pharmaceutical dosage form.

18. For tablets, the present invention claims a material layer capable of carrying a stable holographic pattern that is needed to be coated onto a core. This coating presented additional problems that had to be overcome, including how to reconstruct an effective holographic image without "twinning" of the tablets during coating when using the common method of pan coating. The products described in my EP '821 and U.S. '523 patents, the candies made by LightVision, utilized dehydration in a flat mold to create a holographic element. This resulted in flat holographic elements, a shape conducive to the formation of holographic displays, but not the shape of many dosage forms. Also, flat

surfaces promote twinning during pan coating. Numerous tablet shapes were tried. Injection molding was also tried. Pending claims 25 to 28 define a dosage form shape that can produce the desired, durable holographic image effect while resisting twinning.

19. I discovered that certain edible materials, termed thermoformable in the present application, can also be characterized by their ability to produce stable holographic images and effects over the product life of a pharmaceutical dosage form. As noted above in paragraph 11, these thermoformable materials can become flowable, and then very rapidly harden into a form that is suitably stable for a pharmaceutical application. The flowing and hardening were found to be able to receive and retain a fine pattern of microscopic dimensions (about ½ micron typical depth and able to interact with light), and retain this pattern during de-molding and other applied external forces and environmental effects such as temperature and humidity. Some of the tested product samples of holographic dosage forms according to the present invention made in 1999 have remained stable for over 7 years.

20. I also discovered that certain waxes and certain other materials that I disclose and claim can be add-in constituents of the thermoformable holographic layer. These added constituents can cause the relief pattern to change a controlled way that provides a visual indication of the storage history as a quality control component of the product. They also can influence to adjust the time and degree of heat needed to thermoform a diffraction relief in an outer layer of a pharmaceutical dosage form.

21. Significant other features specified in the pending dependent claims include, but are not limited to: the use of waxes to alter melting and flow characteristics (claims 11,19-21); the use of plasticizers to alter the humidity characteristics of the holographic layer (claim 23); holograms formed into recessed sections to protect from abrasion (claim 28); printing and lamination of a flowable material onto a core (claim 14); and an HPMC to HPC/HPMC physical as well as chemical bonding for labels and a core (claims 15 to 16).

22. Prior to my work to create a holographic pharmaceutical dosage form, I was aware of no pharmaceutical dosage form that created holographic displays, nor of any work of others to create such a product. On information and belief, discoveries defined by the pending claims provide the first successful pharmaceutical dosage form that can produce holographic displays. This work took at least five man-years and substantial investments. Once proven, this invention was licensed to a major pharmaceutical company. It was also cited in now pending patent applications, e.g. U.S. Serial No. 11/236,022 filed September 27, 2005 and published April 27, 2006 under No. 20060088593A1, assigned to a subsidiary or division of Johnson & Johnson. This application cites the present application, my '523 patent, and features described in another co-pending application filed by me in 2004. As evidence of the ongoing industry need for distinctive coloration of pharmaceuticals, I have attached hereto as Exhibit A a newsletter report of a mica product recently introduced by "German drug giant Merck."

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

10/19/06
Date

Eric Begleiter
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